

# Nurofen<sup>®</sup> 12 Hour

Active ingredient(s): *Ibuprofen 300mg*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Nurofen 12 Hour. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Nurofen 12 Hour.**

Where to find information in this leaflet:

- [1. Why am I using Nurofen 12 Hour?](#)
- [2. What should I know before I use Nurofen 12 Hour?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Nurofen 12 Hour?](#)
- [5. What should I know while using Nurofen 12 Hour?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Nurofen 12 Hour?

**Nurofen 12 Hour contains the active ingredient Ibuprofen. Nurofen 12 Hour is a Pharmacist only medicine.** Ibuprofen belongs to a group of non-steroidal anti-inflammatory drugs (NSAID) medications that have pain relieving and fever relieving properties. Nurofen 12 Hour is made to release its ingredient slowly over 12 hours so you need to take less doses than standard tablets.

**Nurofen 12 Hour is used for the temporary relief of pain and inflammation associated with: headache, migraine headache, tension headache, sinus pain, toothache, dental procedures, back pain, muscular aches and pains, arthritis, osteoarthritis, rheumatic pain, period pain, fibrositis, neuralgia, sore throat, tennis elbow, cold and flu symptoms. It also reduces fever.**

## 2. What should I know before I use Nurofen 12 Hour?

### Warnings

**Do not use Nurofen 12 Hour if:**

- you are allergic to any medicines containing Ibuprofen, aspirin or other NSAIDS or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath;
- wheezing or difficulty breathing;
- swelling of the face, lips, tongue or other parts of the body; and
- rash, itching or hives on the skin.

- you have any of the following conditions:
  - liver or kidney disease;
  - heart problems;
  - asthma that is sensitive to aspirin or NSAIDs;
  - a stomach ulcer or duodenal ulcer or if you have had either of these conditions or gastric bleeding or other gastrointestinal diseases in the past.
- if you are taking more than 75mg of aspirin a day.  
If you are on low-dose (up to 75mg daily) speak to your pharmacist before taking this medicine.
- in the last three months of pregnancy. It may affect the baby and also delay labour and birth.
- for children under 12 years of age.
- After the expiry date printed on the pack or if the package is torn or shows signs of tampering. If this medicine has expired or is damaged, return it to your pharmacist for disposal.

### Check with your doctor or pharmacist if you:

- have or have had any other medical conditions
  - asthma;
  - stomach or duodenal ulcer;
  - signs of gastrointestinal bleeding, such as vomiting blood or bleeding from the back passage (rectum);
  - liver or kidney disease;
  - heart problems.
- take any medicines for any other condition
- if you are over 65 years of age.  
Taking this medicine may increase the risk of you getting stomach, heart or kidney problems.
- have allergies to any other medicines, foods, preservatives or dyes.
- are not sure whether you should start taking Nurofen 12 Hour

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Nurofen 12 Hour may affect your developing baby. Your pharmacist or doctor will discuss the benefits and possible risks of taking it during pregnancy.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

This medicine may be taken by breastfeeding mothers; however small amounts of ibuprofen pass into the breast milk.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Nurofen 12 Hour and affect how it works.**

- warfarin, a medicine used to prevent blood clots;
- lithium, a medicine used to treat mood swings and some types of depression;
- medicines used to lower blood pressure;
- methotrexate, a medicine used to treat arthritis and some types of cancer;
- medicines used to treat heart failure;
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system;
- zidovudine, a medicine used to treat HIV infection;
- aspirin, salicylate and other non-steroidal anti-inflammatory drugs (NSAIDs); and
- medicines used to treat diabetes.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Nurofen 12 Hour.**

### 4. How do I use Nurofen 12 Hour?

#### How much to take / use

- Initial dose, 600mg (2 x 300mg tablets). Then if necessary, another 600mg can be taken.
- Leave at least 12 hours between doses and do not exceed 1200mg (4 x 300mg tablets) in 24 hours.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.
- If symptoms worsen, or persist consult a doctor.
- Do not use this medicine in children under 12 years of age.

#### When to take / use Nurofen 12 Hour

- Nurofen 12 Hour should be used at least 12 hours between doses and do not exceed 1200mg (4 x 300mg tablets) in 24 hours.

#### How to take Nurofen 12 Hour

- Take Nurofen 12 Hour with water and swallow whole. Do not chew the tablets.
- Do not take Nurofen 12 Hour for longer than 3 days at a time.

#### If you use too much Nurofen 12 Hour

If you think that you have used too much Nurofen 12 Hour, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while using Nurofen 12 Hour?

#### Things you should do

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Remind any doctor, dentist, or pharmacist you visit that you are using Nurofen 12 Hour.

#### Things you should not do

- Do not take Nurofen 12 Hour to treat any other complaints unless your pharmacist or doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same symptoms as you.
- Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

#### Things to be careful of

- If you are over the 65 years of age, talk to your pharmacist or doctor about taking Nurofen 12 Hour. Taking this medicine may increase the risk of you getting unwanted side effects, such as stomach or heart problems.

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Nurofen 12 Hour affects you.**

#### Drinking alcohol

**Tell your doctor or pharmacist if you drink alcohol.**

#### Looking after your medicine

- Keep your medicine in the original pack until it is time to take it.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 25°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

### [Less serious/common] side effects

Less serious side effects	What to do
<p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>• nausea</li> <li>• heartburn, or stomach pain</li> <li>• loss of appetite</li> <li>• diarrhoea</li> </ul> <p><b>Head and neurology related:</b></p> <ul style="list-style-type: none"> <li>• dizziness</li> <li>• drowsiness</li> <li>• headache or</li> <li>• nervousness</li> </ul>	<p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b></p>

### [Serious/rare] side effects

Serious side effects	What to do
<p><b>Cardiovascular related:</b></p> <ul style="list-style-type: none"> <li>• fluid retention.</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>• vomiting blood or bleeding from the back passage</li> </ul> <p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>• shortness of breath</li> <li>• wheezing or difficulty breathing</li> <li>• swelling of the face, lips tongue or other parts of the body</li> <li>• rash, itching or hives on the skin</li> <li>• get sunburnt more quickly than usual.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

### What Nurofen 12 Hour contains

<b>Active ingredient (main ingredient)</b>	Ibuprofen 300mg
<b>Other ingredients (inactive ingredients)</b>	Colloidal hydrated silica Hypromellose Silicified microcrystalline cellulose Croscarmellose sodium Glycine Stearic Acid Carnauba Wax Opadry Yellow (consisting of hypromellose, quinoline yellow (E104), titanium dioxide, macrogol and polysorbate 80
<b>Potential allergens</b>	N/A

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Nurofen 12 Hour looks like

Nurofen 12 Hour is a white to off-white capsule-shaped tablets debossed with "N12" on one side and plain on the other (AUST R 335682).

Nurofen 12 Hour is available in blister packs\* of 6, 8, 10, 12, 16, 20 or 24 tablets.

\*Not all pack sizes are marketed.

### Who distributes Nurofen 12 Hour

Reckitt Benckiser, Sydney, NSW, Australia

This leaflet was prepared in April 2021.